IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC. and BAYER HEALTHCARE LLC, Plaintiffs, v. BAXTER INTERNATIONAL INC. and BAXTER HEALTHCARE CORPORATION, Defendants.	Civil Action No.: 05-349-GMS Jury Trial Demanded **PUBLIC VERSION**
BAXTER HEALTHCARE CORPORATION, Counterclaimant, v. TALECRIS BIOTHERAPEUTICS, INC. and BAYER HEALTHCARE LLC, Counterdefendants.	

REPLY IN SUPPORT OF SUMMARY JUDGMENT MOTION FILED BY BAXTER INTERNATIONAL INC. AND BAXTER HEALTHCARE CORPORATION

OF COUNSEL:
James G. Gilliland, Jr.
Susan M. Spaeth
Anne M. Rogaski
TOWNSEND AND TOWNSEND and CREW LLP
379 Lytton Avenue
Palo Alto, California 94301
(650) 326-2400

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Philip A. Rovner (#3215)
POTTER ANDERSON & CORROON LLP
Hercules Plaza
P.O. Box 951
Wilmington, Delaware 19899-0951
(302) 984-6000
Email: provner@potteranderson.com

Attorneys for Defendant Baxter International Inc. and Defendant/Counterclaimant Baxter Healthcare Corporation

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I. INTRODUCTION

One would expect the patentee to respond to an indefiniteness challenge by offering clear definitions for the disputed claim terms. Here, however, Plaintiffs Talecris Biotherapeutics, Inc. and Bayer Healthcare LLC ("Plaintiffs") dance around the meaning of "acceptable level [of anticomplement activity 'ACA'] suitable for intravenous administration" throughout their Opposition, without ever providing a definition. While Plaintiffs imply that "acceptable level" should be defined with reference to release limits set by the FDA, they never actually commit to release limits delineating the boundary between an "acceptable level" and an "unacceptable level."

Plaintiffs' refusal to commit to a definition confirms that "acceptable level" is indefinite. Indeed, rather than engage in a traditional indefiniteness analysis, Plaintiffs improperly (and illogically) attempt to prove definiteness through an infringement argument. An indefiniteness analysis must begin with an attempt to identify the boundaries of the claim term at issue. Only if the boundaries can be ascertained is the claim definite and only if the claim is definite should an infringement analysis even be undertaken. Plaintiffs never identify the boundaries of the term "acceptable level" – illustrating that the boundaries are unascertainable.

Even if Plaintiffs intended to delineate the boundaries of "acceptability" by release limits (which would flatly contradict their own expert, Dr. Erwin Gelfand's, opinion that, REDACTED [1]), "acceptable level" remains indefinite.

[1] Declaration of Anne M. Rogaski in Support of Summary Judgment Motion Filed by

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Plaintiffs' experts admit that release limits are constantly changing and that adverse events (which Plaintiffs' experts tie to unacceptable ACA levels) still occur when ACA levels are below release limits. As such, release limits cannot define the boundary between "acceptable" and "unacceptable."

Furthermore, Plaintiffs offer no reasonable response to their own expert's unambiguous admission that "acceptable level suitable for intravenous administration" is indefinite:

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[2]

Plaintiffs also fail to meaningfully respond to the fact that it would be impossible for a manufacturer who does not yet (or ever) have FDA approval to determine the boundaries of claim 1 if release specifications are the standard. In short, Plaintiffs do not rebut Baxter Healthcare Corporation and Baxter International Inc.'s ("Baxter") indefiniteness showing.

Finally, Plaintiffs' recitation of "genuine issues of material fact" are either not material or, in some cases, not in dispute for purposes of this motion. None of those facts precludes summary judgment from being properly granted in this case.

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Baxter International Inc. and Baxter Healthcare Corporation ("Rogaski Decl."), Ex. 3, p. 9.

[2] Rogaski Decl., Ex. 8, p. 196:7-11.

II. PLAINTIFFS OFFER NO DEFINITION OF "ACCEPTABLE LEVEL SUITABLE FOR INTRAVENOUS ADMINISTRATION"

A. Plaintiffs Apply The Wrong Methodology

Plaintiffs acknowledge that claims must have established "boundaries" to be definite, yet never delineate the boundaries of the claim term, "acceptable level suitable for intravenous administration." Because they cannot offer a concrete definition for this term, Plaintiffs approach the question of indefiniteness using an improper methodology. Instead of first ascertaining the boundaries of the claim and then using those boundaries to evaluate infringement and validity, Plaintiffs tautologically argue that, because Baxter's product has been found by the FDA to be releasable[3], it must have achieved "an acceptable level [of ACA] suitable for intravenous administration." But FDA release limits vary from product to product, company to company, and time to time. Consequently, Plaintiffs' hindsight analysis sheds no light on where to draw the actual boundary between "acceptable" and "unacceptable levels" of ACA.

Methodology aside, a careful reading of Plaintiffs' Opposition reveals that they studiously avoid expressly stating that FDA release limits define the boundary between "acceptable" and "unacceptable" levels of ACA. It would have been so easy (and clear) to say so, if release specifications were the standard. Instead, Plaintiffs ambiguously state that release specifications are a "proxy" for "acceptable level," and are based "primarily" on the regulatory process. Opposition at 8-9. The lack of clarity of Plaintiffs' position is

[3] Plaintiffs confuse "acceptable for release" with "acceptable level suitable for intravenous administration" as specifically used in claim 1 of the '191 patent. While the experts generally agree that if ACA meets the FDA release specification, it is "acceptable for release," none of the experts could define "acceptable level suitable for intravenous administration."

directly attributable to (and further evidence of) the indefiniteness of the term "acceptable level suitable for intravenous administration."

B. Release Limits Do Not Define The Boundaries Of "Acceptable" ACA

Assuming Plaintiffs intended to define "acceptable level suitable for intravenous administration" in terms of release limits, such a definition does not adequately identify the boundaries of the claim.[4] One of Plaintiffs' experts, Dr. Gelfand, unequivocally confirmed that release limits cannot define "acceptable level," when he wrote in his expert report: REDACTED

Rogaski Decl., Ex. 3, p. 9. His deposition testimony further confirmed this when he testified, REDACTED

Declaration of Jaclyn Mason in Support of Plaintiffs' Opposition ("Mason Decl."), Ex. 2 at 141:15. A few examples illustrate that release limits do not establish the boundaries of "acceptable level":

1. A manufacturer trying to determine whether to embark on a multi-million dollar IGIV development project would have no guidance to determine whether its proposed process would infringe claim 1 of the '191 patent. Such a manufacturer would have to invest millions of dollars in process development, pre-clinical investigation, clinical trials, etc., before a release limit would even be proposed. Release limits, therefore, provide no guidance[5] as to whether such processes (or

[4] Plaintiffs' reliance on release limits also would shift the responsibility for construing "acceptable level" from this Court to the FDA. Plaintiffs cite no law that would permit the FDA to take on this judicial task.

[5] Even if claim 1 does not require specific ACA numbers for acceptability, Plaintiffs admit that "examples" of acceptable levels are given at column 5:57-64. To determine "acceptability," a manufacturer should be able to compare those examples to its own

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proposed processes) would result in products with "acceptable" ACA.

2. Further, potentially infringing acts include "making" (or manufacturing) IGIV, even if none ever is sold. Though raised by Baxter in its Opening Brief, this fact is virtually ignored in Plaintiffs' Opposition. One who manufactures IGIV products in the U.S., but who does not sell them here, would not be subject to any FDA release limits, so would have no way of determining whether it infringed the patent.

3. Similarly, potentially infringing acts include "use." One who purchases an IGIV product in another country and uses it on U.S. soil may not be using a product subject to FDA release limits. Release limits, therefore, provide no guidance as to whether such a product has an "acceptable" ACA.

4. Products having ACA **above** release limits are sometimes still sold and used in the United States, so are not necessarily "unacceptable." Opening Brief, p. 20; *see also, e.g.*, Rogaski Decl., Ex. 19 at 127:18-130:23 and Ex. 20

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Release limits, therefore, provide no guidance as to whether such products have "acceptable" ACA.

5. Products having ACA levels **below** release specifications may still cause adverse

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product. Doing so, however, would be impossible because (similar to the *Honeywell* case) the '191 patent does not identify the actual proprietary ACA assay used to obtain those numeric examples, and would therefore require comparison of ACA values obtained by different assays (which Plaintiffs acknowledge is not possible). Consequently, the examples in the '191 patent, even if not limiting, further demonstrate the ambiguity associated with the term "acceptable level suitable for intravenous administration."

events. Rogaski Decl., Ex. 3 at 3. Dr. Gelfand's expert report and deposition testimony REDACTED. Rogaski Decl. Ex. 3, p. 2; Mason Decl. Ex. 2, pp. 121:15-122:2. Release limits, therefore, cannot define whether such products have "acceptable" ACA.

6. Plaintiffs' experts made clear that FDA release limits can change over time through negotiation with the FDA. Rogaski Decl., Ex. 3 at 4-5 and 9 and Ex. 4, ¶¶10-11. Because FDA release limits are always subject to change, they cannot provide a concrete boundary for "acceptable level" as used in the '191 patent.

C. Adverse Events Do Not Define The Boundaries Of "Acceptable Level"

Plaintiffs do not address, much less refute, Baxter's arguments regarding adverse events. Baxter highlighted Dr. Gelfand's opinion that REDACTED as inconsistent with Plaintiffs' apparent position that release limits indicate acceptability. Plaintiffs cannot reconcile the fact that IGIV with ACA levels below release specifications may still cause adverse events with a position that release limits define the boundary of acceptability. Plaintiffs instead contend that because of health concerns, manufacturers "desire to have ACA levels that are as low as possible." Opposition at 23. It is entirely unclear whether Plaintiffs are now asserting that "as low as possible" bears on the definition of "acceptable level." If so, Plaintiffs' invocation of "as low as possible" eliminates release specifications as a possible defining boundary for "acceptable level" and introduces yet another source of ambiguity.

D. *Honeywell* And Other Cases Compel A Finding Of Indefiniteness

The term "acceptable level suitable for intravenous administration" is even more indefinite than was the term "having a melting point elevation of 2 to 10 C" in the

Honeywell Int'l, Inc. v. Int'l Trade Comm'n, 341 F.3d 1332 (Fed. Cir. 2003) case. Plaintiffs contend that the lack of a numerical range in claim 1 of the '191 patent avoids application of the *Honeywell* case.[6] Not so. First, claim 1 is **more** indefinite than the term in *Honeywell* because no numerical range is provided by which to determine whether an ACA level is "acceptable." Second, the only examples given in the '191 patent of an "acceptable level"[7] are numerical ranges that were obtained using an undisclosed proprietary ACA assay which cannot be compared against ACA results obtained using a different ACA assay. Consequently, a finding should be made, as it was in *Honeywell*, that the particular assay used to determine the ACA levels is critical to the question of "acceptable level." Similar to *Honeywell*, the named inventor of the '191 patent did not provide any details of Plaintiffs' proprietary ACA assay. While Plaintiffs now point to a C1q assay discussed in the prior art, Plaintiffs cannot dispute that results obtained using such a C1q assay (reported in units of "μg AHG Eq/ml") cannot be compared to the examples given in the '191 patent (reported in CH_{50} units/ml) to

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[6] Plaintiffs separately contend that an invention need not be defined with mathematical precision to be definite, citing *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1341 (Fed. Cir. 2003). Opposition at 16. In the *Oakley* case, however, the Federal Circuit concluded that the numerical examples provided in the patent would affect the interpretation of the claim term at issue ("vivid colored appearance") and read the lower numerical limit from the specification into the claim. The *Oakley* case confirms that, if "acceptable level" is not defined in terms of numerical limits, it is indefinite.

[7] The Patent Office initially rejected "acceptable level" on grounds of indefiniteness. This rejection was only "withdrawn based on the definition of an acceptable level found in the specification at page 9 [*i.e.*, the numerical limits of Col. 5:57-64]." Docket No. 161 at JA83. Plaintiffs misleadingly suggest that the Patent Office withdrew its indefiniteness rejection for both terms "a given level" and "an acceptable level suitable for intravenous administration" based on the substitution of "an increase" for "given level." Opposition at 7. In fact, only the indefiniteness of the term "a given level" was overcome by the substitution of "an increase." "Acceptable level" required a definition expressed in numerical limits before the Patent Office withdrew the indefiniteness rejection.

determine whether the ACA was at an "acceptable level."

Plaintiffs say that the '191 patent requires only "relative" comparisons of whether ACA increased or decreased, but this argument is inapposite. "Acceptable level" is an absolute, not relative, value. The *Honeywell* facts are sufficiently similar to support a similar finding of indefiniteness here, particularly in view of Plaintiffs' experts' testimony demonstrating the indefiniteness of "acceptable level."

Plaintiffs' attempts to distinguish *Halliburton Energy Servs., Inc. v. M-I, LLC*, 456 F. Supp. 2d 811 (E.D. Tex. 2006), and *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342 (Fed. Cir. 2005) also fall short. Plaintiffs seem to argue that an objective standard is provided by FDA release limits, so the claims are not indefinite as they were in *Halliburton* and *Datamize*, where there were only subjective standards. Opposition at 9. But the flaw in that position is that Plaintiffs do not actually equate release limits with a delineation between "acceptable" and "unacceptable." Rather, subjective decisions (such as whether an IGIV product with ACA above release limits may still be sold or whether adverse events with IGIV products having ACA below release limits result from unacceptable ACA levels) impact the question of "acceptability." Accordingly, both *Halliburton* and *Datamize* support a finding of indefiniteness here.

Plaintiffs cite a number of cases regarding "functional claim terms," yet "acceptable level" is not a functional claim term, so these cases are inapposite. Similarly, Plaintiffs point to the *Pharmacia & Upjohn Co. v. Sicor Inc.*, 447 F. Supp. 2d 363 (D. Del. 2006) case, in which the term "physiologically acceptable" was construed. Plaintiffs neglect to mention, however, that there were repeated references in the specification that provided a clear construction of "physiologically acceptable." No such similar language

is found in the '191 patent specification.

E. The Named Inventor's Testimony Should Be Considered

Dr. William Alonso, the named inventor, cannot define "acceptable level" and does not know what it means in his patent. Plaintiffs cite *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372 (Fed. Cir. 2000) for their contention that Dr. Alonso's damning testimony should be disregarded. But, the *Solomon* case presented very different facts from those here. In *Solomon*, the inventor's testimony contradicted the meaning of the claim. Here, Dr. Alonso did not provide contradictory testimony – he provided no testimony at all – about the substantive meaning of the claim term "acceptable level." Rather, Dr. Alonso testified (just like Plaintiffs' expert, Dr. Jeffrey Ravetch) that

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As a person of ordinary skill in the art (under either side's definition), Dr. Alonso's testimony demonstrates that this term has no meaning to a person of ordinary skill. The *Solomon* case does not preclude consideration of Dr. Alonso's testimony for that purpose.

F. No Expert Has Provided A Definition Of "Acceptable Level Suitable For Intravenous Administration"

Plaintiffs ignore much of the testimony of their own experts that Baxter submitted with its Opening Brief and, instead, cite other, contradictory, testimony from those same witnesses. The fact that Plaintiffs' experts contradict themselves does not preclude summary judgment; it simply makes the term "acceptable level suitable for intravenous administration" more – not less – indefinite.

1. Dr. Ravetch

Plaintiffs offer nothing in response to Dr. Ravetch's admission that "acceptable level suitable for intravenous administration" is indefinite; instead, they simply point to

the many times their only infringement/invalidity expert testified that he had not been requested by Plaintiffs' counsel to opine regarding the meaning of the term. While convenient for Plaintiffs (and surprising for a lead expert), this does not change the fact that Dr. Ravetch unequivocally testified:

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That Dr. Ravetch – a self-described person of ordinary skill[9] – does not know what this claim term means demonstrates that it is indefinite.

2. Dr. Cohen

Plaintiffs' Opposition is silent regarding Dr. Pinya Cohen's opinions and testimony identified in Baxter's Opening Brief, despite the fact that Dr. Cohen is Plaintiffs' regulatory expert. Accordingly, this Court must accept the following unrebutted points raised by Dr. Cohen:

1. REDACTED

2. REDACTED

Rogaski Decl., Ex. 11 at 59:3-60:23.

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[8] REDACTED

[9] As Baxter represented in its letters requesting permission to file this motion, it is assuming, only for purposes of this motion, Plaintiffs' experts' testimony and opinions to be true (including Dr. Ravetch's belief that he is a person of ordinary skill). Plaintiffs' experts' testimony and opinions fully support summary judgment of invalidity on indefiniteness grounds.

3. REDACTED

Rogaski Decl., Ex. 4, ¶¶ 10-11; 16.

4. REDACTED

Rogaski Decl., Ex. 11, pp. 54:4-55:9.

Dr. Cohen's opinions further exemplify the indefiniteness of the term "acceptable level suitable for intravenous administration."

3. Dr. Gelfand

Plaintiffs also ignore many of the opinions offered by Dr. Gelfand that Baxter identified in its Opening Brief. For example, Plaintiffs do not respond to:

1. Dr. Gelfand's admission that

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Rogaski Decl., Ex. 3, p. 9.

2. Dr. Gelfand's testimony that

REDACTED

Rogaski Decl., Ex. 10 at 139:20-24.

3. Dr. Gelfand's position that REDACTED

Rogaski Decl., Ex. 3, p. 9.

4. Dr. Gelfand's opinion that REDACTED

Rogaski Decl., Ex. 3, p. 5.

Dr. Gelfand's testimony and expert reports unequivocally establish that the boundary between "acceptable" and "unacceptable" is constantly in flux and, therefore, cannot be

defined. Most significantly, REDACTED contrary to the position Plaintiffs appear to take in their opposition. Dr. Gelfand's opinions preclude release specifications from defining "acceptable level."

4. Dr. Kindt

Dr. Thomas Kindt could not have made more clear in his testimony his belief that "acceptable level" is indefinite. Rogaski Decl., Ex. 18 at 95:5-96:1. Nevertheless, Plaintiffs misleadingly omit Dr. Kindt's complaint about the indefiniteness of this term, as well as his oft-repeated explanation of how he tried to determine whether "acceptable levels" were disclosed in the prior art. For each prior art reference, he identified information showing the author or inventor of the prior art reference believed the ACA level was acceptable or suitable for intravenous administration. Rogaski Decl., Ex. 18 at 82:7-84:24 and 92:7-97:21. Given the ambiguity of the term "acceptable level suitable for intravenous administration" as used in the '191 patent, this was all Dr. Kindt could do in his analysis of the prior art. That he did so does not change his unwavering opinion that this claim term is indefinite.

Apparently realizing that Dr. Kindt never opined that "acceptable level" was capable of being defined, Plaintiffs mischaracterize his testimony, stating, "[t]his was Dr. Kindt's stated definition of 'acceptable ACA level' – commercial product level," when he provided no such definition. Opposition at 11. In fact, the only "definition" Dr. Kindt provided throughout his testimony is that "acceptable level" is indefinite. Rogaski Decl., Ex. 18 at 95:5-96:1.

5. Dr. Snape

Plaintiffs' attempt to use Dr. Snape's testimony regarding FDA release limits for Gammagard Liquid to support its position is similarly futile. As Dr. Snape explained:

> As far as I'm concerned, the release limits are agreed between the manufacturer and the regulatory agency, and only time tells whether the product – if we are talking about a new product – only time tells whether the product is suitable. There will be circumstances in which those release limits may be modified as experience changes.

Mason Decl., Ex. 7 at 134:18-24. Dr. Snape's testimony thus confirms the indefiniteness of "acceptable level."

Plaintiffs have failed to identify any testimony or opinions of the experts in this case which clearly define the term "acceptable level suitable for intravenous administration." Indeed, Plaintiffs' experts make clear that release limits cannot be the defining boundary and that a person of ordinary skill in the art does not know what this claim term means.

III. PLAINTIFFS' ARGUMENT REGARDING "INCREASED LEVEL OF ANTICOMPLEMENT ACTIVITY" RENDERS CLAIM 1 NONSENSICAL

Plaintiffs do not address the obvious fact that if you reduce ACA "to" a level (*e.g.*, an "acceptable level"), it must have been at a different level (*e.g.*, an "unacceptable level") before it was reduced. Plaintiffs' Opposition never squarely addresses this point, or the fact that a reduction of ACA "from" an acceptable level "to" an acceptable level makes no sense.

Instead, Plaintiffs' Opposition parades a litany of confusing and irrelevant positions, none of which directly addresses Baxter's position. For example:

1. Plaintiffs contend that Baxter seeks a second bite at the claim construction apple.[10] Plaintiffs misread Baxter's position. Baxter argues that the claim terms, as construed (not as Baxter sought to have them construed), are indefinite.

2. Plaintiffs attempt to divorce step (a) from step (b) of claim 1, despite express claim language intimately connecting the two. Plaintiffs contend that step (a) "only" requires an increase in ACA and step (b) requires a reduction in ACA levels. Opposition at 25. In fact, however, step (b) clearly requires a reduction of "the increased anticomplement activity" (discussed below) "to an acceptable level."

The unresponsive nature of Plaintiffs' arguments illustrates the indefiniteness and invalidity of the asserted claims.

IV. PLAINTIFFS' DISCUSSION OF "THEN INCUBATING THE SOLUTION OF STEP A)" AND "INCREASED ANTICOMPLEMENT ACTIVITY OF THE SOLUTION" IMPROPERLY READS WORDS OUT OF CLAIM 1

Baxter does not dispute that the Court's construction of "then incubating the solution of step a)" permits intervening steps. The Court's construction did not, however, read words out of claim 1.[11] Claim 1 clearly provides: "… such that **the increased anticomplement**

[10] Notably, where the "plain and ordinary meaning" has not yet been identified, claim construction is not yet complete, and Baxter is entitled to provide its position regarding the plain and ordinary meaning of the terms. None of the cases cited in footnote 12 of Plaintiffs' Opposition suggest that a conclusion that the plain and ordinary meaning applies ends the claim construction inquiry. In fact, in many cases, the court still considered indefiniteness, even if a claim was construed. *Honeywell*, 341 F.3d at 1340; *Datamize,* 417 F.3d at 1356. The *Oakley* court provided a specific construction for a claim term, yet stated, "[t]hat is not to say that Sunglass Hut cannot ultimately succeed on the merits of its indefiniteness argument later in the litigation, after further development of the record." *Oakley*, 316 F.3d at 1342.

[11] Surprisingly, Plaintiffs contend that Baxter is reading terms into claim 1. In fact, Baxter simply contends that all words in claim 1 must be given full effect, including "the increased anticomplement activity of the solution."

activity of the solution is reduced … ." Use of the word "the" in a claim requires that there be some antecedent basis. As noted in *Furminator, Inc. v. Ontel Prods. Corp.*, 429 F. Supp. 2d 1153, 1169 (E.D. Mo. 2006),

> … in the first clause, the term *handle axis* is preceded by the indefinite article 'a' while the second clause uses the definite article 'the.' This use of indefinite and definite articles in a patent claim indicates simply that *the handle axis* referred to in the second clause is the same thing as *a handle axis* referred to in the first clause, according to a universally recognized requirement for precise language in the drafting of patent claims. [] Manual of Patent Examining Procedure § 2173.05(e); *MercExchange, LLC v. eBay, Inc.*, 401 F.3d 1323, 1338 (Fed. Cir. 2005); *North Am. Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1575, 76 (Fed. Cir. 1993) (citing Robert C. Faber, *Landis on Mechanics of Patent Claim Drafting* 351 (3d ed. 1990)); *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 2005 U.S. Dist. LEXIS 15527, at *10-15 (N.D. Ill. July 28, 2005) (citing MPEP § 2173.05(e).

See also Astra Aktiebolag v. Andryx Pharm., Inc., 222 F. Supp. 2d 423, 458 (S.D.N.Y. 2002) ("… the term 'micro-environment' is preceded by the word 'the.' The use of this definite article mandates that the term 'micro-environment' was previously used in claims (*sic*) 1."). Here, "**the** increased anticomplement activity" discussed in step (b) finds antecedent basis in step (a): "… resulting in **an** increased level of anticomplement activity … ." As a result, "the increased anticomplement activity" must be exactly the increased ACA level that resulted from solvent/detergent treatment in step (a). Though processing steps may occur between solvent/detergent treatment and incubation (some of which may affect ACA levels and others that would not), if those steps change the ACA level resulting from solvent/detergent treatment, they necessarily take that process outside the scope of claim 1 because "the increased anticomplement activity" will not be reduced by incuabation.

Plaintiffs miss Baxter's point, as is apparent from Plaintiffs' emphasis on "the increased anticomplement activity **of the solution**," in contrast to Baxter's emphasis on "**the**

increased anticomplement activity of the solution." Regardless of what "solution" is being incubated, it still must have "the increased anticomplement activity" of step (a) when incubation begins to fall within the scope of claim 1. Plaintiffs' argument to the contrary, that "[t]here is no requirement in Claim 1 that the ACA level immediately preceding the step b) incubation must be exactly the same as the level immediately following the solvent/detergent treatment of step a)," would improperly read words ("the increased") out of claim 1.

V. THERE ARE NO DISPUTES AS TO MATERIAL FACTS THAT WOULD PRECLUDE SUMMARY JUDGMENT

In a last-ditch attempt to avoid summary judgment, Plaintiffs identify a number of "issues of material fact" that they contend should preclude summary judgment. None of these issues is "material" to a determination of indefiniteness, and some of these issues are undisputed for purposes of this motion.

First, Plaintiffs discuss the "proper methodology for the particular in-process sample." Opposition at 29. The methodology of measuring ACA of in-process samples is not at issue in this motion, so cannot be "material."

Second, the level of ordinary skill does not preclude summary judgment. Accepting (for purposes of this motion) Plaintiffs' proposed higher level of skill, the terms at issue are still indefinite as exemplified by Plaintiffs' proffered experts' opinions and testimony. Notably, Plaintiffs have not identified a single claim term for which the question of indefiniteness would be resolved differently, depending on the level of skill, so this cannot be "material."

Third, the question whether ACA levels from different assays can be compared to a single standard is not in dispute – all experts agree that ACA results from different assays

cannot be compared.

Fourth, whether FDA release limits provide a standard of "acceptability" is a legal issue for this Court to decide. Notably, Plaintiffs have not actually asserted that FDA release limits are the measure of "acceptability," nor has Baxter, so there appears to be no dispute that release limits are not the standard.

Fifth, the role of adverse events are not in dispute (for purposes of this motion), as Baxter is relying entirely on Plaintiffs' experts' opinions regarding adverse events. To the extent Plaintiffs' experts disagree with each other, or provide internally inconsistent opinions, this simply confirms the indefiniteness of the terms at issue.

There are no disputes of material fact that can preclude summary judgment.

VI. CONCLUSION

Baxter's showing that "acceptable level suitable for intravenous administration," "increased level of anticomplement activity," "then incubating the solution of step a)" and "increased anticomplement activity of the solution" are all indefinite claim terms has not been rebutted by Plaintiffs. Plaintiffs' failure to even offer a definition for, or specifically delineate the boundaries of, these terms demonstrates that they are incapable of definition and their boundaries unascertainable. The undisputed facts for purposes of this motion (*i.e.*, Plaintiffs' experts' reports and testimony) and the case law on indefiniteness compel a

finding that these claim terms are insolubly ambiguous. Consequently, Baxter respectfully requests that claim 1 of the '191 patent, and all asserted claims that depend from claim 1, be adjudged indefinite.

POTTER ANDERSON & CORROON LLP

By: /s/ Philip A. Rovner
Philip A. Rovner (#3215)
Hercules Plaza
P.O. Box 951
Wilmington, Delaware 19899-0951
(302) 984-6000
Email: provner@potteranderson.com

Attorneys for Defendant
Baxter International Inc. and
Defendant/Counterclaimant
Baxter Healthcare Corporation

OF COUNSEL:

James G. Gilliland, Jr.
Susan M. Spaeth
Anne M. Rogaski
TOWNSEND AND TOWNSEND AND CREW LLP
379 Lytton Avenue
Palo Alto, California 94301
(650) 326-2400

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on April 17, 2007, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

BY HAND DELIVERY AND E-MAIL

Jeffrey B. Bove, Esq.
Mary W. Bourke, Esq.
Mark E. Freeman, Esq.
Jaclyn Mason, Esq.
Donna Hallowell
Connolly Bove Lodge & Hutz LLP
1007 N. Orange Street
P. O. Box 2207
Wilmington, DE 19899-2207
jbove@cblh.com, mbourke@cblh.com
mfreeman@cblh.com, jmason@cblh.com
dhallowell@cblh.com; cjeffers@cblh.com;
dhammond@cblh.com; mlambert@cblh.com

BY EMAIL

Dana K. Hammond, Esq.
M. Curt Lambert, Esq.
Connolly Bove Lodge & Hutz LLP
1007 N. Orange Street
Wilmington, DE 19899
jhammond@cblh.com; mlambert@cblh.com

Christopher E. Jeffers, Esq.
Connolly Bove Lodge & Hutz LLP
1990 M. Street, NW
Washington, DC 20036-3425
cjeffers@cblh.com

I hereby certify that on April 17, 2007 I have sent by E-mail and Federal Express the foregoing document to the following non-registered participants:

Bradford J. Badke, Esq.
Gabrielle Ciuffreda, Esq.
Ropes & Gray LLP
1211 Avenue of the Americas
New York, NY 10036-8704
bradford.badke@ropesgray.com
gabrielle.ciuffreda@ropesgray.com

/s/ Philip A. Rovner
Philip A. Rovner (#3215)
Potter Anderson & Corroon LLP
Hercules Plaza
P. O. Box 951
Wilmington, DE 19899
(302) 984-6000
provner@potteranderson.com